IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ABBOTT DIABETES CARE INC. ET AL,

Plaintiff,

v.

ROCHE DIAGNOSTICS CORPORATION ET AL,

Defendant.
_____/

No. C04-02123 MJJ
No. C04-03327 MJJ
No. C04-03732 MJJ
No. C05-03117 MJJ

CLAIMS CONSTRUCTION ORDER

INTRODUCTION

Before the Court are Therasense, Inc., Abbott Diabetes Care, Inc. and Abbott Laboratories (collectively, "Abbott"), Roche Diagnostics Corporation and Roche Diagnostics Operations, Inc. (collectively, "Roche"), Bayer Healthcare LLC ("Bayer"), Nova Biomedical Corporation ("Nova"), and Becton, Dickinson and Company's ("Becton") proposed constructions of disputed terms in two Patents held by Abbott. The parties filed numerous briefs and joint claims construction statements submitting proposed constructions of the disputed terms. On March 9, 2007, the Court held a claim construction hearing lasting several hours. The Court, having considered the parties' papers, oral arguments, evidence, and the patents-in-suit, now construes the disputed terms as follows.

FACTUAL BACKGROUND

The patents at issue are U.S. Patent No. 5,820,551 ("the '551 Patent") entitled "Strip Electrode of Screen Printing," and U.S. Patent No. 6,592,745 ("the '745 Patent") entitled "Method of Using a Small Volume in Vitro Analyte Sensor with Diffusible or Non-Leachable Redox

Mediator." The patents-in-suit concern disposable test strips that are inserted into the meters that diabetics typically use to test their blood glucose concentrations. The strips utilize electrochemical techniques to accomplish this purpose.

The only claim at issue in the '551 Patent is Claim 1. It provides:

> 1. A single use disposable electrode strip for attachment to the signal readout circuitry of a sensor to detect a current representative of the concentration of a compound in a drop of whole blood sample comprising:
> a) an elongated support having a substantially flat, planar surface, adapted for releasable attachment to said readout circuitry;
> b) a first conductor extending along said surface and comprising a conductive element for connection to said readout circuitry;
> c) an active electrode on said strip in electrical contact with said first conductor and positioned to contact said whole blood sample;
> d) a second conductor extending along said surface comprising a conductive element for connection to said readout circuitry; and
> e) a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample, wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member and is formed by coating a portion of the first conductor with a mixture of or layers of an enzyme which catalyzes a redox reaction with said compound in whole blood and a mediator compound which transfers electrons from said redox reaction to said first conductor to create a current representation of the concentration of said compound in said whole blood sample; and wherein said active electrode which is formed on a portion of said conductor is not in electrical contact with said reference counterelectrode but these electrodes are so dimensioned and positioned that they can be simultaneously completely covered by a single drop of whole blood such that this drop provides an electrical path between these electrodes to support said current representation of the concentration of said compound in said whole blood sample.

The claim elements at issue in the '745 Patent are found in each of independent Claims 1, 24, and 28. They provide, in turn:

> 1. A method for determining a concentration of glucose in a sample, comprising the steps of:
> (a) contacting a sample with an electrochemical sensor comprising:
> (I) an electrode pair comprising a working electrode and a counter electrode, wherein the measurement zone is sized to contain a volume of no more than about 1 L of the sample; and
> (ii) a measurement zone positioned adjacent to the working electrode and the counter electrode, wherein the measurement zone is sized to contain a volume of no more than about 1 L of the sample; and
> (iii) an analyte-responsive enzyme and a diffusible redox mediator disposed in the measurement zone;

(b) holding the sample within the measurement zone in a non-flowing manner;
(c) generating a sensor signal at the working electrode within a measurement period of no greater than about 5 minutes, wherein a background signal that is generated by the redox mediator is no more than five times a signal generated by oxidation or reduction of 5 mM of glucose;
(d) determining the concentration of the glucose using the sensor signal.

28. A method for determining a concentration of glucose in a sample, comprising steps of:
(a) contacting a sample with an electrochemical sensor comprising:
(I) a working electrode and counter electrode, wherein the working electrode and counter electrode are separated by a closest distance of no greater than 1000 µm;
(ii) measurement zone positioned adjacent to the working electrode and the counter electrode, wherein the measurement zone is sized to contain a volume of no more than about 1 µL of the sample; and
(iii) an analyte-responsive enzyme and a diffusible redox mediator disposed in the measurement zone;
(b) holding said sample within the measurement zone in a non-flowing manner;
(c) generating a sensor signal at the working electrode within a measurement period, wherein a back ground signal that is generated by the redox mediator is no more than five times a signal generated by oxidation or reduction of an average normal physiological amount of analyte; and
(d) determining the connection of the glucose by amperometry using the sensor signal.

34. A method for determining a concentration of glucose in a sample, comprising steps of:
(a) contacting a sample with an electrochemical sensor comprising:
(I) an electrode pair comprising a working electrode and counter electrode, wherein the working electrode and counter electrode are separated by a closest distance in a range of 200 to 1000 µm;
(ii) measurement zone positioned adjacent to the working electrode and the counter electrode, wherein the measurement zone is sized to contain a volume of no more than about 1 µL of the sample; and
(iii) an analyte-responsive enzyme and a diffusible redox mediator disposed in the measurement zone;
(b) holding said sample within the measurement zone in a non-flowing manner;
(c) generating a sensor signal at the working electrode within a measurement period, wherein a back ground signal that is generated by the redox mediator is no more than five times a signal generated by oxidation or reduction of an average normal physiological amount of analyte; and
(d) determining the connection of the glucose using the sensor signal

DISPUTED CLAIM TERMS

A. The '551 Patent

The disputed claim terms in the '551 Patent are as follows:

- "an active electrode on said strip in electrical contact with said first conductor";
- "reference counterelectrode in electrical contact with said second conductor"; and
- "wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member."

B. The '745 Patent

The disputed claim terms in the '745 Patent are as follows:

- "positioned adjacent to the working electrode and the counter electrode"; and
- "background signal that is generated by the redox mediator."

LEGAL STANDARD

The construction of a patent is a matter of law for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). In construing terms, the Court must conduct an independent analysis of the claim terms; it is insufficient to simply choose between the competing constructions that the parties have submitted. *Exxon Chem. Patents v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995). To determine the meaning of a patent claim, the Court primarily considers three sources: (1) the claims; (2) the specification; and (3) the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd, Markman*, 517 U.S. 370.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Accordingly, in construing disputed terms, the Court first looks to the words of the claims. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Generally, the Court ascribes the words of a claim their ordinary and customary meaning. *Id.* "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective

filing date of the patent application." *Phillips*, 415 F.3d at 1313.

Other claims of the patent in question can also assist in determining the meaning of a claim term. *Vitronics*, 90 F.3d at 1582. Because an inventor normally uses claim terms consistently throughout a patent, the usage of a term in one claim may reveal the meaning of the same term in other claims. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). Conversely, use of a term in a different way in another claim may also be useful in determining the particular meaning of the disputed term. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991). Particularly, the existence of a dependent claim that adds a particular limitation creates a presumption that the limitation in question is not present in the independent claim. *Liebel-Flarseim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987).

Because the claims are part of a fully integrated written instrument comprised principally of the specification, the Court must next review the specification. *Markman*, 52 F.3d at 978-79. Because the specification must contain a description of the invention that is clear and complete enough to enable those of ordinary skill in the art to make and use it, the specification is "always highly relevant" to the Court's claim construction analysis. *Vitronics*, 90 F.3d at 1582. "Usually, [the specification] is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* "In light of the statutory directive that the inventor provide a 'full' and 'exact' description of the claimed invention, the specification necessarily informs the proper construction of the claims." *Phillips*, 415 F.3d at 1316. In some cases, the specification may reveal that the patentee has given a special definition to a claim term that differs from its ordinary meaning. "In such cases, the inventor's lexicography controls." *Id.* at 1316. The specification also may reveal the patentee's intentional disclaimer or disavowal of claim scope. "In that instance, as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." *Id.* Thus, the specification can act as a dictionary when it expressly or impliedly defines terms used in the claims. *Id.*

Next, in addition to reviewing the specification, the Court should consider the patent's prosecution history, if it is in evidence. *Markman*, 52 F.3d at 980. The prosecution is intrinsic

evidence and consists of the complete record of the proceedings before the Patent and Trademark Office ("PTO") and includes the prior art cited during the examination of the patent. *Phillips*, 415 F.3d at 1317. "The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower then it would otherwise be." *Phillips*, 415 F.3d 1317; *see also Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.") (internal quotations omitted).

In addition to the foregoing intrinsic evidence, the Federal Circuit has also authorized district courts to rely on extrinsic evidence in claim construction, which consists of "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.' *Markman*, 52 F.3d at 980. However, extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004). "Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various field of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." *Phillips*, 415 F.3d 1318. Accordingly, the Court may consider this evidence, if the Court deems it helpful in deciphering the true meaning of the claim terms. *Id.*

ANALYSIS

I. Claims Construction of the '551 Patent.

A. "an active electrode on said strip in electrical contact with said first conductor"

The parties first disagree over whether an "active electrode" comprises just an enzyme and mediator (Abbott's proposed construction), or an enzyme, mediator, and conductive material (Defendants' construction). The parties also disagree whether "in electrical contact with said first conductor" means that the conductive material in the active electrode is required to be a separate structure from the first conductor.

1. Summary of the Parties' Arguments

Generally speaking, Abbott argues that the "active electrode" is a mixture of or layers of an enzyme and mediator, that is "in electrical contact" with the first conductor because it is capable of transferring electrons from the redox reaction to the first conductor. Abbott proffers that its construction is based on the plain language of the claim itself, and is supported by the specification, whereas Defendants' improperly rely on extrinsic evidence in support of their proposed construction.

Defendants contend that an electrode, by definition, contains a conductive material, and further seek a construction that emphasizes the "active electrode" as a separate and distinct structure from the first conductor. They rely on, among other things, the specification, the prosecution history, and several sources of extrinsic evidence to support their construction, including testimony by the Patent's inventors, and Abbott's position in a prior litigation.

In response, Abbott argues that it is inappropriate to construe "active electrode" as requiring a conductive material. To the extent that a conductive element is necessary to make the invention work, Abbott reiterates that it is supplied by the first conductor itself, but contends that it is not necessary to have a conductive element in an "active electrode" as that term is used in the '551 Moreover, Abbott argues that Defendants' proposed construction improperly requires two conductive layers, the first being part of the "separate" electrode, and the second being the first conductor - a construction Abbott argues would improperly exclude embodiments of the invention described in the specification.

2. Discussion

a. Whether the "active electrode" must include conductive material.

The claim language states that the active electrode "is formed by coating a portion of the first conductor with a mixture of or layers of an enzyme which catalyzes a redox reaction with said compound in whole blood and a mediator compound . . ." '551 Patent at col. 14:1-6. The Court disagrees with Abbott that this language plainly indicates that the active electrode is comprised of only the active chemistry (enzyme and mediator). Nothing in the claim language so specifies, and it can just as easily be interpreted to indicate that the active electrode includes a portion of the first

conductor. Moreover, the Court finds that the claim term "active electrode" itself requires construction independent of the subsequent and narrowing "formed by" claim limitation. To do otherwise would improperly read the term "active electrode" out of the claim.

The Court finds that the specification does not conclusively resolve whether the "active electrode" necessarily includes conductive material, but generally weighs in favor of the viewpoint that it does. Most persuasively, the '551 Patent's Abstract describes "[a]n active electrode, positioned to contact the liquid mixture and the first conductor, comprises a single layer deposit of an enzyme capable of catalyzing a reaction involving the compound, a conductive material and an electron mediator." This is the closest that the specification comes to providing a general description of an "active electrode" that is not limited to a specific embodiment. Defendants also point to other embodiments that include a conductive material in the active electrode. '551 Patent at 2:6-11 ("the active electrode is formed by printing . . . an ink comprising a conductive compound, the enzyme, and the mediator . . ."); 3:18-32 (referring to conductive electrode); 4:35-46 (active electrode is preferably formed on carbon e.g., a filter paper containing carbon). However, Abbott points to a portion of the specification that describes an active electrode that "comprises a deposit of enzyme capable of catalyzing a reaction" (*id.* at 1:55-65), as well as a passage referencing "immobilized glucose oxidase in the presence of a mediator compound as the electron-transfer electrode" (*id.* at 12:1-3.) Though Abbott contends that the term "active electrode" cannot be construed to require a conductive element in light of these passages, neither actually excludes a conductive element. In patent parlance, the term "comprising" is understood to be synonymous with "including, and allows the inclusion of unnamed components. *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp., Inc.*, 123 F.3d 1445, 1451 (Fed. Cir. 1997).[1]

Abbott concedes that it is common for electrochemists to refer to the collective combination

[1]For the same reason, Abbott's citation to other claims in the patent application is not determinative, because these application claims make the same use of the word "comprising." (Abbott's Initial Markman Brief, Exhs. 3-6.) Similarly, Abbott's citation to the application materials from the related '844 and '548 patents (Abbott's Initial Markman Brief, Exhs. 8-16) is not persuasive, because the '551 claims are not directed to an admixture of enzyme, mediator, and conductive material. That other patents specify that the active electrode includes the enzyme, conductor, and mediator when referring to such an admixture does not mean that the '551 active electrode does not include a conductor.

of the enzyme, mediator, and conductor as the electrode. (Abbott's Initial Markman Brief, 12:7-8.)[2] Abbott attempts to distinguish the instant matter by asserting that the patentee chose to differentiate between the conductor on the one hand, and the active chemistry on the other. The patentee can act as his or her own lexicographer, but must clearly set forth a definition of a claim term that is different from the term's ordinary and customary meaning. *Intellectual Property Development, Inc. v. UA-Columbia Cablevision*, 336 F.3d 1308, 1316 (Fed. Cir. 2003). Abbott has not directed the Court's attention to any such clear language within the specification, and indeed the general description of the active electrode in the Abstract (discussed above) cuts against Abbott's attempt to establish a special definition that refers only to the active chemistry.

The Court next turns to the prosecution history, and finds that it provides even stronger support for construing "active electrode" to require a conductive element. The Court disagrees with Abbott's assertion that, in the prosecution history, "[w]hen discussing the active electrode, Abbott consistently characterized it as containing only enzyme and mediator or only enzyme...." (Abbott's Initial Markman Brief at 9:22-24.) To the contrary, to obtain issuance of the '551 patent, Abbott submitted a declaration to the Examiner which distinguished the '551 invention from, *inter alia*, U.S. Patent No. 4,897,173 (a piece of contemporaneous art). Abbott's declarant, Dr. Sanghera, specifically cited Example 4 from the '173 Patent, which contained a filter below the enzyme and mediator layers and above only the conductive elements, as an example that demonstrated that "the authors of this technical disclosure still believe that active electrodes could not be directly exposed to whole blood samples." (Bartlett Decl. Ex. 16 at ¶ 6.) Given that the filter only protected the conductive element in Example 4, Abbott's declarant necessarily was acknowledging that the "active electrode" was not limited to the enzyme and mediator layers, as otherwise the declarant's statement that Example 4 showed its authors believed an active electrode could not be exposed to whole blood would not make sense. Further support comes from the applicant's contemporaneous remarks accompanying the December 4, 1997 amendment to the patent application, in which the patentee stated that "the present application has clear support for an active electrode for a whole

[2]Dictionary definitions do not resolve whether the "active electrode" includes conductive material, but generally favor Defendants' position. The dictionary definitions of "electrode" submitted by the parties generally support Defendants' argument that an electrode includes conductive material.

blood sample formed from coating a mixture or layers of an enzyme and a mediator on a conductive electrode...." (Abbott's Initial Markman Brief Exh. 7 at TH0044144, emphasis added).

The Court next turns to the extrinsic evidence submitted by Defendants. Contrary to Abbott's assertion, the Court may exercise its discretion to consider extrinsic evidence where such evidence "can help the court determine what a person of ordinary skill in the art would understand claim terms to mean", although the Court must remain mindful that extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317-19. Here, in particular, the Court finds that testimony from one of the '551 inventors is useful for assessing how "active electrode" would be understood by one with ordinary skill in the art. The testimony in question was proffered by Abbott in prior litigation and is directly on point, but now directly undercuts Abbott's proposed construction in this litigation. In the *LifeScan* litigation, Abbott submitted the declaration of co-inventor Professor Hill, who testified unambiguously that:

> All those in the art would use the term "active electrode" (and enzyme electrode) to refer to an electrode made up of both a conductive material (such as a conductive layer of carbon) and the active chemistry (including the enzyme, and optionally a mediator). No one in the art would consider either the active chemistry alone or the conducting layer alone to be an 'active electrode.'"

(Bartlett Decl. Exh. 10 at ¶6, emphasis in original).[3] The Court considers this extrinsic evidence only in the context of the intrinsic evidence already discussed above, and finds it consistent with the construction arrived at by the Court.

In light of the above, the Court agrees with Defendants that an "active electrode" includes an enzyme, mediator, and conductive component. The Court now turns its attention to whether the claim requires that the electrode and first conductor be separate structures.

b. Whether the active electrode's conductive element must be a separate structure from the first conductor.

Having determined that "active electrode" necessarily includes a conductive element,

[3]The Court has also reviewed the testimony given by three of the four '551 inventors in this case. (Bartlett Decl. Exh. 11; Guerra Decl. Exhs. D & E.) This testimony is less clear-cut and the Court does not consider it sufficiently reliable for use in construing the claim term. The Court declines to rely on this testimony to construe the '551 patent.

Defendants ask the Court to further specify in its construction that the conductive material of the active electrode must be a separate structure from the conductive material in the first conductor. The Court declines to do so based on its review of the '551 patent's specification. The '551 patent discloses embodiments in which there may be a single, integral piece of conductive material, where the active electrode is formed on a part of this piece of conductive material. '551 Patent at 8:58-9:18 (Example 1, Figures 3 & 4), 9:42-59 (Figure 7). For example, Figures 3 and 4 depict embodiments where the pad of conductive material that is part of the active electrode is contiguous with the first conductor itself. In Figure 3 the strip "includes a square area 18 with a connector lead, the square being covered with the enzyme-containing layers as described above. It further includes a small reference electrode area 20 and separate conductor lead 21." *Id.* at 8:59-63. Though Defendants point to embodiments where the active electrode (including its conductive element) are distinct and separate from the conductive element (*see, e.g.*, '551 Patent at 4:58-60, 4:66-5:12, 8:22-46), this does not provide a basis for building a "separateness" requirement into the claim language. The Court concludes that the claim language should be construed to include both embodiments where the conductive material in the active electrode is a separate structure from the first conductor, and those embodiments where it is not.

Moreover, the wording of claim 1 appears inconsistent with a requirement that the conductive portion of the active electrode be a separate structure from the first conductor. Claim 1 itself describes the active electrodes as being "formed by coating a portion of the first conductor with a mixture of or layers of an enzyme . . . and a mediator compound. . .", and describes the active electrode as "formed on a portion of said conductor." '551 Patent at 14:3-6, 14:10-11. This claim language strongly suggests that the active electrode can be created by incorporating the conductive material already present in the first conductor. *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351 (Fed. Cir. 2006), cited by Defendants, is distinguishable here. In *SRAM*, the court construed the term "fixed handgrip on the end of the handlebar" to mean a separate handgrip situated over a handlebar. *Id.* at 1359-60. In contrast, here, the claim language "formed by coating", "and "formed on a portion of" are not consistent with requiring the conductive portion of the active electrode be a separate structure from the first conductor.

The Court also disagrees with Defendants that the claim language "in electronic contact" by definition means that the conductive material of the active electrode and the conductive material in the first conductor must be separate structures. In embodiments in which the conductive material in the active electrode is part of a single, integral piece of conductive material, the active electrode and the first conductor will still be in "electrical contact" such that electricity can flow between them.[4]

The Court does not find the extrinsic evidence submitted by Defendants to point towards a different result. First, the selected non-technical dictionary definition of "contact" submitted by Defendants (meaning "union or junction of surfaces" or "the junction of two electrical conductors through which a current passes") (Bartlett Decl. Exh. 12) does not require two separate structures, and in any event the concept of being in "electrical contact" to one skilled in the art is distinct from that of being in "contact." Second, contrary to Defendants' characterization, the testimony of Dr. Sanghera and Dr. Davis (Bartlett Decl. Exhs. 11 & 13) does not directly discuss whether the conductive element of the active electrode and the first conductor must be two separate structures.

In light of the foregoing, the Court construes "an active electrode" to mean "an electrode that incorporates conductive material, and a mixture of or layers of an enzyme and mediator", and further construes "in electrical contact with said first conductor" to mean "such that the active electrode is connected or positioned in such a way that electricity can flow between the active electrode and the first conductor."

B. "reference counterelectrode in electrical contact with said second conductor"

The parties have stipulated, and the Court agrees, that the term "counterelectrode", as used in the term "reference countereelectrode" in the '551 Patent, refers to "an electrode that is used to complete an electrical circuit with the active electrode during the glucose measurement."[5]

The parties' dispute concerns the reference electrode component of the "reference counterelectrode." Abbott contends that a reference electrode is important because the active

[4] The Court agrees with Abbott that one end of a copper wire would be considered in "electrical contact" with the other end because electricity can flow from one end to the other, even though the wire itself is a single, integral piece.

[5] Abbott contends that there is no reason that the term "countereelectrode" should be defined for the jury. The Court, however, does not believe that counterelectrode is a term that the jury can be expected to understand on its own, and will therefore include an explanation of this term in its construction.

electrode is "poised at a fixed potential against a reference electrode," '551 Patent at 8:15-18, not because the reference electrode itself is fixed against a known standard potential. As such, Abbott asserts its proposed construction appropriately emphasizes this feature of the reference potential. In addition, Abbott asserts that Defendants' construction is overly restrictive since the issue of a "fixed" potential is relative, and the potential of any real world reference electrode will always vary slightly during its operation. Abbott proffers that a person of skill in the art understands that the term "fixed potential" means that the potential may vary by a minor amount. Abbott also cites to *Electrochemical Methods Fundamentals and Application* by Dr. Allen Bard for the proposition that a reference electrode merely "approaches ideal nonpolarizability." *Electrochemical Methods Fundamentals and Application* at 25, 2nd Ed. (2001).

Defendants' proposed construction, on the other hand, emphasizes the purported properties of the reference electrode itself. The specification describes the process of determining the potential of a palladium-silver reference electrode by substituting it into an electrochemical system previously calibrated with a saturated calomel electrode (SCE) - a known standard. '551 Patent at 10:6-12. In addition, the specification notes that the potential of the palladium-silver "was stable, i.e., did not drift, over 48 hours of operation." *Id.* at 10:13-14. They also point out that Dr. Bard explicitly defines a reference electrode as "an electrode of known potential" and that the Bard treatise shows that the potential of an actual reference electrode that approaches ideal nonpolarizability is consistent with the potential of an ideal nonpolarized electrode at small currents (i.e., at small currents, the an actual reference electrode maintains a fixed potential). (*See* Guerra Decl., Exh. G at 22.) Defendants tie this to the '551 Patent with deposition testimony from one of the inventors who says that the two electrode system in the invention works because the current is relatively small and does not affect the potential of the reference electrode.

Abbott responds that the silver-palladium reference electrode discussed in the specification likely did not drift because it was operating under ideal conditions. By contrast a reference electrode in contact with blood is not operating under ideal conditions would likely drift. Abbott characterizes such a reference electrode as akin to a "quasireference" or "pseudoreference" and note that the Patent teaches that the reference can be "any convenient reference electrode." '551 Patent at 4:53-

57. As such, contends Abbott, the invention will work with any type of reference electrode so long as the potential difference between the working and reference electrodes is relatively constant.

Having considered the parties arguments, the Court agrees in part with Defendants. While Abbott is correct in saying that the function of the reference electrode is to poise the working electrode at a particular potential, the specification teaches that the reference electrode of the claimed invention does this precisely because the reference electrode is of a known potential relative to a standard. Abbott fails to explain how using a reference without a know potential relative to a standard would allow the invention to accurately measure glucose levels. Similarly, although the specification notes that any convenient reference can be used, Abbott fails to point to any portion of the specification that teaches the use of a quasireference, pseudoreference, or other type of reference. Rather, the specification focuses on a reference electrode with a known potential as the means for maintaining a substantially constant bias between the reference electrode and the working electrode.

The Court, however, finds that the "fixed" language in Defendants' proposed construction is too restrictive. The one reference in the specification that the palladium-silver reference electrode's potential did not drift over 48 hours of operation does not mean that there was no variation whatsoever in potential during this time. Further, Defendants have offered nothing suggesting that minor variations in the potential of the reference electrode would vitiate the reference's electrode's ability to maintain a "substantially constant bias voltage." *See* '551 Patent at 2:22-25. Bayer admits that "fixed" does not require an "impossibly 'perfect' reference electrode," just one that "while the device is measuring glucose . . . peg[s] the potential relative to a known standard." (Bayer Reply at 14:22-15:1.) Roche argues that the construction need not expressly acknowledge that some small variation in potential is normal since "people refer to values as 'fixed' or 'set' yet understand that some minor deviation occurs . . ." (Roche Reply at n.8.) Becton/Nova proffers: ". . . if the Court finds that a person of skill would understand that fixed potential allows for some degree of variation from a known reference point, that variation must be insignificant if the electrode is to serve as a meaningful reference." (Becton/Nova Opposition at 6.)

Finally, the parties disagree about whether the reference counterelectrode needs to be a separate structure from the second conductor. For the same reasons discussed above in connection

with the active electrode and first conductor, the Court finds that no such requirement should be built into this claim language.

Consistent with the above analysis, the Court construes "reference counterelectrode in electrical contact with said second conductor" to mean "an electrode that (1) is used to complete an electrical circuit with the active electrode during the glucose measurement; (2) is positioned or connected in such a way that electricity can flow between the second conductor and the electrode, (3) has a known potential relative to a standard, and (4) maintains its potential with only insignificant variation during the measurement."

C. "wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member" (hereafter at times "the filter limitation")

1. Collateral Estoppel[6]

As a threshold matter, Becton/Nova asserts that Abbott should be collaterally estopped from "relitigating" the construction of the filter limitation. More particularly, in *Abbott Labs v. LifeScan, Inc.*, 37 F. Supp. 2d 70 (D. Mass. 1999), the court rejected Abbott's construction of the filter limitation within the context of Abbott's motion for a preliminary injunction. Abbott here proposes the same construction for the filter limitation that it sought in *LifeScan*. Becton/Nova contends that Abbott had a full and fair chance to litigate its position on the meaning of this term during the *LifeScan* preliminary injunction proceedings and should be precluded from arguing the same flawed construction here. Abbott responds that preliminary injunction rulings are not sufficiently firm to serve as a basis for collateral estoppel and that collateral estoppel does not apply to settled cases or cases dismissed without prejudice, such as the *LifeScan* case.

The doctrine of collateral estoppel prevents the re-litigation of issues actually litigated and necessarily decided, after a full and fair opportunity for litigation, in a prior proceeding. *Kourtis v. Cameron*, 419 F. 3d 989, 994 (9th Cir. 2005). A prior decision has preclusive effect where: (1) the issue necessarily decided at the previous proceeding is identical to the one which is sought to be

[6]In connection with earlier related cases, Becton/Nova filed a motion to collaterally estop Abbott from rearguing the claim construction ruling from the *LifeScan* litigation. (Case No. C 04-2123, Doc. No. 150.) Abbott opposed the Motion. (*Id.*, Doc. No. 169.) The Court struck the motion as premature because the terms of the '551 Patent were not yet at issue. (*Id.*, Doc. No. 176.) The parties have now re-raised the collateral estoppel issue as part of their claim construction submissions.

relitigated; (2) the first proceeding ended with a final judgment on the merits; and (3) the party against whom collateral estoppel is asserted was a party or in privity with a party at the first proceeding. *Id.* However, collateral estoppel does not attach merely because the same issue is raised in successive suits.

The parties' dispute centers on element two of the collateral estoppel inquiry – whether the first proceeding ended with a final judgment on the merits. Becton/Nova contends that Abbott's focus on the type of proceeding, and the fact that the case settled before trial, elevates form over substance. Becton/Nova contends that Abbott had ample opportunity to be heard, and there was nothing more the *LifeScan* Court, needed to consider, or could have considered, to resolve the construction of the filter limitation – a legal question. Becton/Nova points out that in the earlier litigation: (1) Abbott had the benefit of three months of pre-hearing discovery; (2) the LifeScan court held a three-day hearing, about half of which was dedicated to attorney argument on the issue of claim construction; (3) the parties engaged in three rounds of briefs, (4) the only claim construction issue briefed by the parties post-hearing was the construction of the filter limitation, and (5) the *LifeScan* decision denying the motion for preliminary injunction hinged on the construction of the filter limitation, and the court's construction was based on the intrinsic record.

The *LifeScan* court held:

> The determinative phrase in this case is that the active electrode must be " configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member." The ordinary and natural meaning of the phrase "without an intervening membrane or other whole blood filtering member" is without any type of filter whatsoever-neither an intervening membrane nor any other whole blood filter. The absence of any filter was the innovation of the '551 patent and plaintiff's products are manufactured with no whole blood filter. Based on the evidence submitted, the Court finds that the FastTake® product does contain a whole blood filter, and, consequently it does not infringe Abbot's patent.

LifeScan, 37 F. Supp. 2d at 72.

Abbott did not appeal the preliminary injunction ruling. After several more years of litigation, the parties settled the case and dismissed it without prejudice.

Abbott does not contest these facts, but insists that preliminary injunction rulings, and particularly claim construction rulings reached during preliminary injunction proceedings, are not

sufficiently firm to be afforded collateral estoppel effect. Abbott also argues that collateral estoppel should not apply here because the *LifeScan* dispute was settled before trial and dismissed without prejudice.

When applying collateral estoppel law in a patent infringement case, the law of the circuit in which the district court sits controls. *Bayer AG. v. Biovail Corp*., 279 F.3d 1340, 1345 (Fed. Cir. 2002). Under Ninth Circuit law, to be "final" for collateral estoppel purposes, a decision need not possess "finality" in the sense of 28 U.S.C. § 1291. *Luben Indus., Inc. v. United States*, 707 F.2d 1037, 1040 (9th Cir. 1983). Instead, a final judgment for purposes of collateral estoppel is any prior adjudication of an issue in another action that is determined to be "sufficiently firm" to be accorded preclusive effect. *Id*. The Ninth Circuit has set forth several factors that should be considered when determining whether an order is sufficiently firm: "(1) whether the decision was not avowedly tentative; (2) whether the parties were fully heard; (3) whether the court supported its decision with a reasoned opinion; and (4) whether the decision was subject to an appeal." *Id.*

After considering the authorities and facts cited by the parties, the Court concludes that these factors, on balance, counsel against applying collateral estoppel to the *LifeScan* preliminary injunction ruling. In particular, applying the first factor, though the *LifeScan* court permitted considerable briefing and argument as to the construction of the filter limitation, its decision appears nonetheless to have been tentative for claim construction purposes. The record reflects that the *LifeScan* court was solely concerned with determining whether Abbott was likely to succeed on the merits at trial. Though claim construction is a legal issue, this does not mean that in a preliminary injunction context the *LifeScan* court necessarily gave as thorough consideration to the construction as it would have had the litigation gone to trial. The tentative nature of the *LifeScan* court's construction is evident both from the wording of the preliminary injunction decision (*Abbott v. LifeScan*, 37 F. Supp. 2d 70 (D. Mass. 1999)) and from the hearing itself, during which Judge Harrington apparently anticipated later conducting a full *Markman* hearing or construing the patent terms during the course of the trial. (January 26, 1999 Hearing Transcript at p. 4.) Though Becton/Nova speculates that the finality of the filter limitation construction is shown by the fact that the *LifeScan* court never again addressed claim construction during the four subsequent years of

litigation before settlement, there is no evidence in the record before this Court further clarifying the *LifeScan* court's intentions in this regard.

Ninth Circuit precedent also supports the conclusion that preliminary injunction decisions should generally be considered tentative. *See Kuzinich v. County of Santa Clara*, 689 F.2d 1345, 1350-51 (9th Cir. 1982) ("issues litigated in a preliminary injunction action . . . do not form a basis for collateral estoppel"); *Starbuck v. City and County of San Francisco*, 556 F.2d 450, 457 n. 13 (9th Cir. 1977) ("granting a preliminary injunction . . . . is not a final judgment sufficient for collateral estoppel purposes"). The Federal Circuit has also observed that claim constructions for purposes of preliminary injunctions are often tentative in nature:

> District judges are overburdened and need flexibility to operate efficiently. They deserve tolerance by reviewing courts so they can tailor procedures of adjudication to the case at hand." District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves. This is particularly true where issues involved are complex, either due to the nature of the technology or because the meaning of the claims is unclear from the intrinsic evidence. Indeed, these difficulties may be even more acute in the preliminary injunction context than at later stages in the litigation because, as was the case here, motions for a preliminary injunction may come for decision before significant discovery has occurred. Hence, in reviewing a district court's decision on a motion for a preliminary injunction, we remain mindful that all findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits.

Jack Guttman, Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002) (quotations and citations omitted); *see also Abbott v. Andrx Pharmaceuticals, Inc.*, 47 3F.3d 1196, 1205-06 (Fed. Cir. 2007) (preliminary injunction ruling not given collateral estoppel effect under Seventh Circuit law because it did not "clearly intend[] to firmly and finally resolve the issue").

In light of the tentative nature of the claim construction reached at the preliminary injunction stage in *LifeScan*, the last three factors articulated by the Ninth Circuit do not sway the Court towards applying collateral estoppel here. Though Abbott was given considerable opportunity to be heard on the construction of the filter limitation, those proceedings do not appear to have taken the construction of other, related claim terms into account. The *LifeScan* court supported its preliminary injunction finding with a published, reasoned opinion, but this written opinion itself reflects the

tentative nature of the construction reached therein. Finally, the fact the Abbott did not exercise its right to appeal the denial of the preliminary injunction under 28 U.S.C. § 1292 does not convert the tentative claim construction reached therein into a "sufficiently firm" final ruling. Moreover, the parties settled the *LifeScan* dispute before trial and dismissed it without prejudice, preventing the possibility of any appeal relating to claim construction after entry of judgment. *Cf. RF Delaware, Inc. v. Pacific Keystone Technologies, Inc.*, 326 F.3d 1255, 1259-61 (Fed. Cir. 2003) (applying Eleventh Circuit law to find no collateral estoppel applied to claim construction where extrajudicial settlement was reached before entry of judgment).

2. Claims Construction

Abbott argues that the plain language of the claim, and the prosecution history, shows that the claim was only meant to exclude membranes or filter layers placed on top of the entire active electrode. In other words, Abbott asserts that the claim excludes only those embodiments that use a filter or membrane to prevent the enzyme and mediator from coming in to contact with whole blood, but includes embodiments where the filtering occurs after such contact. Defendants, by contrast, assert that the claim language and the prosecution history support the conclusion that the claim requires all components of the active electrode to come into contact with whole blood.

The disputed term provides: "wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member." Abbott urges that the plain meaning of this term makes clear that the claim excludes only membranes or filters placed between the blood sample and the active electrode. The Court disagrees. While the term "intervening membrane" could possibly be construed as a membrane placed between the blood and active electrode, the claim also explicitly excludes "other whole blood filtering member[s]." The term "other whole blood filtering member" is not modified in any fashion. The presence of the adjective "other" in this claim phrase is inconsistent with Abbott's attempt to link the adjective "intervening" as a modifier of "whole blood filtering member." As such, the claim language itself is most appropriately read as requiring that the active electrode is configured to be exposed to whole blood without the use of *either* an intervening membrane, or some other whole blood filtering device, without regard as to where the other whole blood filtering

device is positioned.

Because the filter limitation was added during prosecution to overcome patentability problems, the specification does not shed much light on the meaning of the filter limitation. However, the prosecution history of the '551 Patent strongly supports the Court's interpretation of the claim language. The patent examiner's Interview Summary states that the applicant was interested in submitting claims covering an electrode with the filtering member absent. The Examiner determined that a prior patent (Higgins *et al.* '382) appeared to require the use of a membrane with whole blood, and that an affidavit or other evidentiary showing from the '551 applicant that at the time of the invention such a membrane was considered essential would overcome this teaching. (Mehta Decl., Exh. 3.) In response, the '551 applicants relied on U.S. Patent No. 4,897,173 to Nankai, *et al.* to make this evidentiary showing. The applicants compared Nankai's disclosure of a filterless glucose testing device (Example 3) that utilized just plasma (which lacks the whole blood components that can interfere with the sensor), and the disclosure of a filtered device for testing whole blood (Example 4) to establish that those skilled in the art, at the time of the invention, believed that filters were necessary when testing whole blood. (*Id.* at Exh. 4, THO007883.) But Nankai Example 4 contained a filter that was placed between the enzyme/mediator and the conductive element. *See* '173 Patent at 5:38-6:38 & Fig. 8 (Bartlett Decl. Exh. 16). In Example 4, once the whole blood is added to the sensor, the enzyme and mediator are "dissolved in and permitted to react with the blood." *Id.* at 5:66-67. The applicants' use of Example 4 – in which the only component of the active electrode not permitted to encounter the whole blood was the conductive portion – to establish that filters were considered necessary when testing whole blood is further evidence that the '551 claims, as issued, cannot permit a filter that prevents a portion of the active electrode to react with whole blood. The Court considers this intrinsic evidence to be consistent with, and to provide further support for, its reading of the plain language of the claim.

In contrast, Abbott's proposed construction would permit a filter that lets a portion of the active electrode to interact with whole blood. Abbott contends that Nankai Example 4 actually supports its proposed construction. In Nankai Example 4, the filter is located between the enzyme/mediator layer and conductive element. A whole blood sample is allowed to react with the

enzyme/mediator at the same time filtration occurs. The filtrate collects in a liquid retaining layer which brings the reaction solution in contact with the electrode. '173 Patent at 5:38- 6:7 (Mehta Decl., Exh. 5.) Abbott argues that since an active electrode must be in electrical contact with the first conductor in the '551 patent claims, in Nankai the active electrode is only formed when the whole blood is added and the reaction solution is gathered onto the electrode. At this point, asserts Abbott, the filter is actually on top of the active electrode. Accordingly, Abbott argues, to the extent the applicant distinguished Nankai Example 4 from the invention, the applicant only distinguished embodiments where the filter is placed over the entire active electrode. Abbott's argument, however, is not persuasive. The applicant's statements regarding Nankai Example 4 were not directed at patentability over the Nankai reference overall (as Nankai was not prior art), but were directed specifically at the filter limitation, and the applicant cited to Example 4 as an example of how the "art continued to believe that a barrier layer for whole blood sample was necessary for a considerable period" in contrast to his invention. (Mehta Decl., Exh. 4 at TH0007883.) Accordingly, while the Court does not consider the applicant's statements regarding Nankai Example 4 to be such a clear disavowal of scope as to constitute a surrender of material that would otherwise be covered by the claims, the Court does regard the applicant's statements regarding Nankai Example 4 to provide further support for its reading of the plain meaning of the claim language.

Moreover, the applicant included argument distinguishing its invention from the prior art in the same amendment, stating: "There is no teaching or suggestion of ***unprotected active electrodes*** for use with whole blood specimens in this patent or the other prior art of record in this application." (Mehta Decl. Exh. 4 at TH0007884, emphasis added.) The applicant's reference to active electrodes as "unprotected" is inconsistent with Abbott's proposed construction and provides further support for the Court's reading of the patent claims.[7]

[7] Abbott's other contentions that the claims were drafted to exclude only situations where the enzyme and mediator were exposed to whole blood are dependent upon this Court agreeing with Abbott's proposed construction of "active electrode", which it does not. For example, the fact that the applicant explained during prosecution that the purpose of a membrane was to filter out larger molecules or other blood components "expected to interfere with the active electrode's operation" (Plf's Initial Markman Brief, Exh. 7 at TH0044144) would support Abbott's position only if the "active electrode" were defined as requiring only an enzyme and mediator.

Accordingly, the Court rejects Abbott's proposed construction as inconsistent with the claim language, and the '551 Patent's prosecution history. As to Bayer and Roche's proposed constructions, the Court finds them redundant in light of the fact that the Court has already defined what an active electrode is. By contrast, Becton/Nova's construction is incomplete since it only addresses one component of the active electrode.

The Court therefore construes the claim phrase "wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member" to mean "such that the active electrode is exposed to whole blood during measurement and no part of the active electrode is prevented from being exposed to the whole blood sample through use of a intervening membrane or any other component that filters whole blood."

II. Claim Construction of the '745 Patent.

A. "measurement zone positioned adjacent to the working electrode and the counter electrode"

All parties agree that the measurement zone is defined by the '745 Patent to be "a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during an analyte assay." '745 Patent at col. 7:7-9. The parties' dispute centers on the placement of the measurement zone and specifically on the meaning of the term "adjacent." Abbott first argues that a jury can easily understand what it means for the measurement zone to be "adjacent" to the electrodes such that there is no need for the Court to construe the term. However, the evidence submitted by the parties indicates that "adjacent" is susceptible to several different meanings depending on context. The Court disagrees with Abbott that the ordinary meaning of the term "adjacent" is precise enough to render a construction unnecessary. The Court therefore turns to the specification and other evidence submitted by the parties for further guidance. *Phillips*, 415 F. 3d at 1315.

Here, the specification does not define the term adjacent nor discuss the measurement zone being adjacent to the electrodes. However, as Defendants point out, the term adjacent does appear in other places in the specification. Because an inventor normally uses terms consistently throughout a patent, the usage of a term in one part of the patent may reveal the meaning of the same term in other parts of the patent. *See Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). However, the Court is also mindful that "unless compelled to do otherwise, a court will give a claim

term the full range of its ordinary meaning as understood by an artisan of ordinary skill." *Id.* at 1342.

Defendants assert that because "adjacent" is used in the specification to describe items that are apparently in contact with each other, that the meaning of the word must be restricted to "in contact." For example, Defendants assert that because the electrodes 1010 and 1020 in Figure 31A (which are described as "adjacent" in the specification, *see* '745 Patent at 34:53) appear to touch each other, "adjacent" necessarily means "touching" for purposes of '745 claim language. However, nothing in the patent states that the electrodes in Figure 31A actually touch; this is merely an interpretation of the Figure proffered by Defendants. The patent itself merely describes these electrodes as "next to each other" ('745 Patent at 31:54-61) when contrasting them to the electrodes shown in Figure 31B, which are described as "spaced apart" ('745 Patent at 31:59-61). Defendants also point to the description of forming a non-conductive material "adjacent" to the working electrodes to provide a planar surface, which would appear to require the non-conductive material to touch the electrode to create the smooth surface and reduce the likelihood of air bubbles. ('745 Patent at 32:4-10.) While this does appear to be an example where items described as "adjacent" are actually touching, this does not necessarily mean that the meaning of "adjacent" in the claim terms must be restricted to items that are touching. The patentee repeatedly uses different terms, including the words "in contact", throughout the specification to specify that must touch each other. In the Court's view, the patentee's use of the term "adjacent" in the specification does not provide adequate basis to restrict the meaning of the term to "in contact."

Indeed, the Court disagrees with Defendants that construction of the term "adjacent" requires the Court to make a mutually-exclusive choice between a definition that requires contact or a definition that does not let items touch each other. The Court has reviewed the dictionary definitions submitted by the parties as part of their Joint Claim Construction submission. Here, the use of the term "adjacent" in the '745 Patent is most consistent with dictionary definitions requiring nearness and the lack of an intervening object, without either requiring or prohibiting that the objects in question actually touch each other. *See, e.g.*, Oxford English Dictionary, 2nd ed., 1989 ("Adjacent: Lying near or close (to); adjoining, continuous, bordering. (Not necessarily touching, though this is

by no means precluded.)"); Webster's Third New International Dictionary, Unabridged, 2002 ("relatively near and having nothing of the same kind intervening...") The Court will therefore apply this customary and ordinary meaning absent some other basis for restricting the term "adjacent" to objects in actual contact. *Philips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005).

Defendants urge that "adjacent" must require actual contact here, regardless of its ordinary meaning, in light of the invention and the problem to be solved, which are proper considerations for the Court to consider when construing claim terms. *See CVI/Beta Ventures, Inc. v. Tura LLP*, 112 F. 3d 1146, 1160 (Fed. Cir. 1997). Specifically, the measurement zone, as jointly construed by the parties, contains only that portion of the sample that is to be interrogated during an analyte assay. Defendants point out that the '745 Patent teaches that the working electrode picks up electrons from the reduced mediator molecules in the sample, and the electrons then flow through the meter to yield a glucose measurement. '745 Patent at 79:66-10-6. Defendants contend that, in order for this to happen, the working electrode therefore must be in contact with the measurement zone. Similarly, Defendants contend that the shuttling problem addressed by the '745 invention could only occur if the measurement zone is in contact with both the working and counter electrodes. The Court, however, does not find these arguments a persuasive basis for abandoning a meaning of "adjacent", supported by both the specification and dictionary references, that permits, but does not require, touching.

Abbott suggests that "adjacent" should be construed only to require that the measurement zone be "positioned close to" the working electrode and counter electrode, citing one specific dictionary definition. However, the Court finds this proposed construction to be both too broad and too indefinite for application by a jury.

Accordingly, the Court construes "measure zone positioned adjacent to the working electrode and the counter electrode" to mean "the measurement zone is next to (whether or not touching) both the working electrode and counter electrodes, with no other structure intervening between either electrode and the measurement zone."

B. "background signal that is created by the redox mediator"

Abbott proposes a broad construction of this term encompassing all sources of background

signal. Abbott is correct that the specification teaches that the background signal corresponds to the charge passed in an electrochemical assay in the absence of the analyte. '745 Patent at 9:57-59. Abbott is also correct that the specification discusses several potential components of the background signal. *See* '745 Patent at 38:15-18, 50:27-32, 54:66-55:54 (background signal caused by interferents); 9:51-10:15 (background signal caused by shuttling of the redox mediator);49:44-48 (background signal caused by mediator already in reduced form). However, the plain language of the claim speaks to "background signal *that is created by the redox mediator*." Background signal created by interferents, for example, is not "generated by the redox mediator" as required by the claim itself. Abbott's proposed construction improperly reads limitations out of the claim. *See Glaxo, Inc. v. Novopharn, Ltd.*, 110 F. 3d 1562, 1566 (Fed. Cir. 1997).

Defendants, on the other hand, propose a more narrow construction, limiting the source of the background signal to the shuttling of a diffusible redox mediator. The claim language and specification lend strong support for Defendants' proposed construction. First, the "Background of the Invention" identifies the mediator shuttling problem as one of the problems addressed by the claimed invention. ('745 Patent at 1:49-59.) Second, the claim elements that refer to a background signal generated by a redox mediator specify a particular ratio of background signal to analyte signal, no more than 5 times a signal generated by oxidation or reduction of 5mM of glucose. The specification, in turn, discusses this ratio at length, and describes how to specifically calculate this very same ratio by comparing the glucose signal to the signal from the shuttling of the redox mediator. ('745 Patent at 10:48-59, 11:50-64.) Indeed, the specification provides specific formulas for calculating the ratio referenced in the patent claims, and does so in each instance by providing a formula that takes into account the shuttling of the redox mediator only, as compared to the glucose signal. ('745 Patent at 39:12-40:23.) Accordingly, the claim language's reference to the "background signal that is created by the redox mediator" is best understood as a performance characteristic that is measured by the tests described in the specification, which take into account only the background shuttling of the redox mediator. *See Pall v. Micron Separations, Inc.*, 66 F.3d 1211, 1216-17 (Fed. Cir. 1995) (affirming construction of "skinless" as a performance characteristic measured by tests described in specification). Given the specification's clear guidance as to how to

measure this performance characteristic, the Court is not convinced by Abbott's citation to other portions of the specification indicating that the redox mediator may potentially contribute to the background signal in ways other than shuttling. (*E.g.* '745 Patent at 9:60-63, 49:44-48.) For purposes of the performance characteristic stated in the claims and defined in the specification, the background signal generated by the shuttling of the redox mediator is the relevant input.

Defendants also assert that the Court's construction of this term should make clear that there must be some signal generated by the shuttling. As such, they propose that the Court include the language "a signal must be present." As Abbott points out, however, the claim language itself only requires that the background signal "is no more than five times a signal generated by oxidation or reduction of 5mM of glucose . . ." *Id.* at 61:59-61. A background signal of zero meets this limitation. Moreover, Defendants point to nothing in the claim language itself, or in the specification, that supports their position that the claimed invention requires some background signal to be present.

Accordingly, the Court construes the term "background signal that is created by the redox mediator" to mean "the background signal that is created by the shuttling of the redox mediator back and forth between the working and counter electrodes during the measurement period."

CONCLUSION

For the foregoing reasons the Court construes the disputed terms as follows:

'551 Patent:

- "an active electrode" as "**an electrode that incorporates conductive material, and a mixture of or layers of an enzyme and mediator**";
- "in electrical contact with said first conductor" as "**such that the active electrode is connected or positioned in such a way that electricity can flow between the active electrode and the first conductor**";
- "reference counterelectrode in electrical contact with said second conductor" as "**an electrode that (1) is used to complete an electrical circuit with the active electrode during the glucose measurement; (2) is positioned or connected in such a way that electricity can flow between the second conductor and the electrode,**

(3) has a known potential relative to a standard, and (4) maintains its potential with only insignificant variation during the measurement";

- "wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member" as "**such that the active electrode is exposed to whole blood during measurement and no part of the active electrode is prevented from being exposed to the whole blood sample through use of a intervening membrane or any other component that filters whole blood**";

'745 Patent:

- "measure zone positioned adjacent to the working electrode and the counter electrode"as **"the measurement zone is next to (whether or not touching) both the working electrode and counter electrodes, with no other structure intervening between either electrode and the measurement zone**"; and
- "background signal that is created by the redox mediator" as "**the background signal that is created by the shuttling of the redox mediator back and forth between the working and counter electrodes during the measurement period**."

IT IS SO ORDERED.

Dated: 4/24/2007

MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE